IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, AKTIEBOLAGET DRACO, KBI INC. and KBI-E INC.,	)	
Plaintiffs,	)	Civil Action No. 08-305-JJF
v.	)	
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.,	)	**DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**
Defendants.	)	**JURY TRIAL DEMANDED**

DEFENDANTS BARR LABORATORIES, INC.
AND BARR PHARMACEUTICALS, INC.'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Barr Laboratories, Inc. ("Barr Labs") and Barr Pharmaceuticals, Inc. ("Barr Pharmaceuticals") (collectively referred to herein as "Barr") answer the Complaint of Plaintiffs AstraZeneca LP, Aktiebolaget Draco, KBI Inc. ("KBI") and KBI-E Inc. ("KBI-E") and assert counterclaims as follows:

1. Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Complaint, and therefore denies these allegations.

2. Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and therefore denies these allegations.

3. Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, and therefore denies these allegations.

4. Barr is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 4 of the Complaint, and therefore denies these allegations.

5. Barr admits that Barr Labs is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 223 Quaker Road, Pomona, New York, 10970. Barr admits that Barr Labs does business in the State of Delaware.

6. Barr admits that Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 223 Quaker Road, Pomona, New York 10970. Barr admits that Barr Pharmaceuticals does business in the State of Delaware. Barr admits that Barr Pharmaceuticals is the parent of Barr Labs, and Barr Labs is a wholly-owned subsidiary of Barr Pharmaceuticals.

7. Denied.

Jurisdiction and Venue

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that this Court has subject matter jurisdiction over Plaintiffs' claims under 28 U.S.C. §§ 1331 and 1338(a). Barr denies any and all remaining allegations set forth in Paragraph 8 of the Complaint.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that this Court has personal jurisdiction over Barr Labs for purposes of this action. Barr denies any and all remaining allegations set forth in Paragraph 9 of the Complaint.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that this Court has

personal jurisdiction over Barr Pharmaceuticals for purposes of this action. Barr denies any and all remaining allegations set forth in Paragraph 10 of the Complaint.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that venue for this action is proper in this Court. Barr denies any and all remaining allegations set forth in Paragraph 11 of the Complaint.

Claim I for Patent Infringement

12. Barr incorporates by reference its answers to the allegations in paragraphs 1 through 11 above as if fully set forth herein.

13. Upon information and belief, Barr admits that the United States Patent and Trademark Office issued United States Patent No. 6,423,340 ("the '340 patent") on July 23, 2002 and that it is entitled "Method For The Treatment Of Inflammatory Bowel Diseases." Barr admits that a copy of the '340 patent is attached to the Complaint as Exhibit A. Barr denies any and all remaining allegations set forth in paragraph 13 of the Complaint.

14. Upon information and belief, Barr admits that Aktiebolaget Draco is the owner of the '340 patent. The claims of the '340 patent speak for themselves, and the '340 patent is attached to the Complaint as Exhibit A. Barr denies any and all remaining allegations set forth in paragraph 14 of the Complaint.

15. Barr lacks knowledge and information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 15 of the Complaint, and therefore denies these allegations. Upon information and belief, Barr admits that AstraZeneca LP is the holder of approved New Drug Application ("NDA") No. 21-324. Barr denies any and all remaining allegations set forth in paragraph 15 of the Complaint.

16. Barr lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint, and therefore denies these allegations.

17. Barr admits that Barr Labs submitted an ANDA to the United States Food and Drug Administration ("FDA") under § 505(j).

18. Barr admits that in a letter dated April 9, 2008, Barr Labs stated that it filed an ANDA with the FDA. Barr admits that this letter notified Aktiebolaget Draco and AstraZeneca LP that Barr Labs' ANDA was submitted under 21 U.S.C. §§ 355(j)(1), with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in Barr Labs' opinion and to the best of its knowledge, the '304 patent is invalid, unenforceable, and/or will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in the ANDA. Barr denies any and all remaining allegations set forth in paragraph 18 of the Complaint.

19. Denied.

20. Denied.

21. Barr admits that the filing of an ANDA containing a Paragraph IV certification to an Orange Book listed patent vests this court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Barr specifically denies that Barr Labs' ANDA infringes the '340 patent and the remaining allegations set forth in paragraph 21 of the Complaint, including any implication that the '340 patent is valid and enforceable.

22. Denied.

23. Denied.

24. Denied.

Claim II for Patent Infringement

25. Barr incorporates by reference its answers to the allegations in paragraphs 1 through 24 above as if fully set forth herein.

26. Upon information and belief, Barr admits that the United States Patent and Trademark Office issued United States Patent No. 5,643,602 ("the '602 patent") on July 1, 1997 and that it is entitled "Oral Composition For The Treatment Of Inflammatory Bowel Disease." Barr admits that a copy of the '602 patent is attached to the Complaint as Exhibit B. Barr denies any and all remaining allegations set forth in paragraph 26 of the Complaint.

27. Upon information and belief, Barr admits that Aktiebolaget Draco is the owner of the '602 patent. The claims of the '602 patent speak for themselves, and the '602 patent is attached to the Complaint as Exhibit B. Barr denies any and all remaining allegations set forth in paragraph 27 of the Complaint.

28. Barr lacks knowledge and information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 28 of the Complaint, and therefore denies these allegations. Upon information and belief, Barr admits that AstraZeneca LP is the holder of approved New Drug Application ("NDA") No. 21-324. Barr denies any and all remaining allegations set forth in paragraph 28 of the Complaint.

29. Barr lacks knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint, and therefore denies these allegations.

30. Barr admits that Barr Labs submitted an ANDA to the FDA under § 505(j).

31. Barr admits that in a letter dated April 9, 2008, Barr Labs stated that it filed an ANDA with the FDA. Barr admits that this letter notified Aktiebolaget Draco and

AstraZeneca LP that Barr Labs' ANDA was submitted under 21 U.S.C. §§ 355(j)(1), with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in Barr Labs' opinion and to the best of its knowledge, the '602 patent is invalid, unenforceable, and/or will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in the ANDA. Barr denies any and all remaining allegations set forth in paragraph 31 of the Complaint.

32. Denied.

33. Denied.

34. Barr admits that the filing of an ANDA containing a Paragraph IV certification to an Orange Book listed patent vests this court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Barr specifically denies that Barr Labs' ANDA infringes the '602 patent and the remaining allegations set forth in paragraph 34 of the Complaint, including any implication that the '602 patent is valid and enforceable.

35. Denied.

36. Denied.

37. Denied.

38. The "WHEREFORE" paragraph following paragraph 37 of the Complaint and the seven lettered paragraphs that follow it state Plaintiffs' prayer for relief, to which no response is required. To the extent a response is required, Barr denies the allegations set forth in the "WHEREFORE" paragraph following paragraph 37 of the Complaint and the seven lettered paragraphs that follow it and denies that Plaintiffs are entitled to any of the relief requested therein, or to any relief whatsoever.

39. Any allegation of the Complaint not expressly admitted herein is hereby denied.

AFFIRMATIVE DEFENSES

Barr sets forth the following affirmative and other defenses. Barr does not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden.

First Defense

The manufacture, use, offer to sell, sale, and/or importation of Barr Labs' budesonide drug product has not infringed, does not infringe, and would not, if marketed, infringe, or induce or contribute to such conduct, any valid and enforceable claims of the '340 patent.

Second Defense

The manufacture, use, offer to sell, sale, and/or importation of Barr Labs' budesonide drug product has not infringed, does not infringe, and would not, if marketed, infringe, or contribute to such conduct, any valid and enforceable claims of the '602 patent.

Third Defense

The claims of the '340 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

Fourth Defense

The claims of the '602 patent are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and/or 116 of Title 35 of the United States Code.

Fifth Defense

Plaintiffs have failed to state any claim upon which relief can be granted against Barr Pharmaceuticals.

Sixth Defense

Plaintiffs lack standing to assert claims against Barr for infringement of the '340 and '602 patents.

Seventh Defense

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Barr Laboratories, Inc. ("Barr Labs") brings the following counterclaims against Plaintiffs AstraZeneca LP, Aktiebolaget Draco, KBI Inc. ("KBI") and KBI-E Inc. ("KBI-E") for a declaratory judgment that United States Patent Nos. 5,643,602 ("the '602 patent") and 6,423,340 ("the '340 patent") are invalid and not infringed by Barr Labs' ANDA product.

Parties

1. Counterclaim-Plaintiff Barr Labs is a corporation organized and existing under the laws of Delaware, has its principal place of business at 223 Quaker Road, Pomona, New York 10970, and does business in the State of Delaware.

2. On information and belief, Counterclaim-Defendant AstraZeneca LP is a limited partnership organized and existing under the laws of the State of Delaware, and has its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850-5437.

3. On information and belief, Counterclaim-Defendant Aktiebolaget Draco is a corporation organized and existing under the laws of Sweden and has its principal place of business at Lund, S-221 00, Sweden.

4. On information and belief, Counterclaim-Defendant KBI is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

5. On information and belief, Counterclaim-Defendant KBI-E is a Delaware corporation having its principal place of business at Wilmington, Delaware.

Jurisdiction and Venue

6. The counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 and 21 U.S.C. 355(j)(5)(C).

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1338(a), 2201 and 2202 and 21 U.S.C. 355(j)(5)(C).

8. This Court has personal jurisdiction over Counterclaim-Defendants AstraZeneca LP, Aktiebolaget Draco, KBI and KBI-E on the basis of, *inter alia*, their contacts with Delaware relating to the subject matter of this action, including having filed suit.

9. This Court also has personal jurisdiction over Counterclaim-Defendants AstraZeneca LP and KBI-E on the basis of, *inter alia*, AstraZeneca LP and KBI-E's continuous and systematic contacts in Delaware, and their derivation of substantial revenue from services or things produced or consumed in Delaware.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

Background

FDA Approval Of New Brand Name Drugs

11. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the United States Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

12. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

13. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) – (c)(2); 21 C.F.R. § 314.53(b)(1) – (c)(2).

14. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

15. The FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e) – (f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

FDA Approval Of New Generic Drugs

16. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

17. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

18. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

19. To receive FDA approval of its ANDA, an applicant must show, inter alia, that its generic drug is "bioequivalent" to the reference listed drug, and that it contains the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling as the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a).

20. If the applicant meets these requirements, it is entitled to rely on the NDA holder's clinical studies performed on the reference listed drug to show the product's safety and efficacy.

21. An ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

22. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

23. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

24. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

25. Patent holders have a significant strategic incentive to list patents in the Orange Book and file suit within 45 days of receiving notice of a paragraph IV certification because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court action. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, for example, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

Acts Giving Rise To Barr's Counterclaims

26. Based on the allegations of Plaintiffs' Complaint, Counterclaim Defendants have rights to the '340 patent and the '602 patent.

27. Barr Labs filed with the FDA an ANDA with a Paragraph IV Certification to obtain approval to engage in the manufacture, use or sale of a drug product containing budesonide. In its ANDA, Barr certified pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV)

("Paragraph IV") of the act that, in Barr Labs' opinion and to the best of its knowledge, the claims of the '340 and the '602 patents are invalid and/or not infringed by the commercial manufacture, offer to sell, sale, and/or use of the drug product described in Barr Labs' ANDA.

28. On April 9, 2008, Barr Labs sent Counterclaim Defendants AstraZeneca LP and Aktiebolaget Draco a statutorily-required notice letter containing a detailed factual and legal statement as to why the '340 and '602 patents were invalid, unenforceable and/or not infringed by Barr Labs' ANDA product. Within its notice letter and pursuant to 21 U.S.C. § 355(j)(5)(C), Barr Labs offered to provide its ANDA to Plaintiffs. On May 22, 2008, Plaintiffs filed their patent infringement lawsuit against Barr. Barr was served with Plaintiffs' Complaint on May 23, 2008. In the Complaint, Plaintiffs allege that Barr Labs' ANDA product will infringe the '340 and '602 patents, which Barr has denied herein.

The '340 Patent

29. On information and belief, the United States Patent and Trademark Office issued the '340 patent on July 23, 2002. The '340 patent lists Jan Ulmius as the inventor and Aktiebolaget Draco as the assignee. A true and correct copy of the '340 patent is attached as Exhibit A to Plaintiffs' Complaint.

30. The '340 patent is entitled "Method For The Treatment Of Inflammatory Bowel Diseases" and describes methods comprising the oral administration of budesonide for the treatment of ulcerative colitis and Crohn's colitis in its active phase, and as relapse preventing therapy for Crohn's colitis in its chronic phase and Crohn's disease in the small intestine.

31. Based on the allegations set forth in Plaintiffs' Complaint and Barr Labs' Answer, a justiciable controversy exists between those parties with respect to the validity and scope of the claims of the '340 patent.

The '602 Patent

32. On information and belief, the United States Patent and Trademark Office issued the '602 patent on July 1, 1997. The '602 patent lists Jan Ulmius as the inventor and Astra Aktiebolag as the licensee. Upon information and belief, Aktiebolaget Draco is the owner of the '602 patent. A true and correct copy of the '602 patent is attached as Exhibit B to Plaintiffs' Complaint.

33. The '602 patent is entitled "Oral Composition For The Treatment Of Inflammatory Bowel Disease" and is directed to an oral composition described for targeted slow release in the treatment of inflammatory bowel diseases and pharmaceutical compositions described for peroral treatment targeted to different areas of the intestinal tract afflicted by ulcerative colitis and certain aspects of Crohn's disease.

34. Based on the allegations set forth in Plaintiffs' Complaint and Barr Labs' Answer, a justiciable controversy exists between those parties with respect to the validity and scope of the claims of the '602 patent.

35. This case is an exceptional one and Barr Labs is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

First Counterclaim

36. Barr Labs hereby repeats and reiterates the allegations of paragraphs 1 through 31 and paragraph 35 as if fully set forth herein.

37. The manufacture, use, offer to sell, sale and/or importation into the United States of Barr Labs' ANDA product does not infringe, induce infringement, or contribute to infringement by another of the '340 patent.

Second Counterclaim

38. Barr Labs hereby repeats and reiterates the allegations of paragraphs 1 through 28 and 32 through 35 as if fully set forth herein.

39. The manufacture, use, offer to sell, sale and/or importation into the United States of Barr Labs' ANDA product does not infringe, induce infringement, or contribute to infringement by another of the '602 patent.

Third Counterclaim

40. Barr Labs hereby repeats and reiterates the allegations of paragraphs 1 through 31 and paragraph 35 as if fully set forth herein.

41. The '340 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, or 116 of Title 35 of the United States Code.

Fourth Counterclaim

42. Barr Labs hereby repeats and reiterates the allegations of paragraphs 1 through 28 and 32 through 35 as if fully set forth herein.

43. The '602 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, or 116 of Title 35 of the United States Code.

WHEREFORE, Defendant and Counter-plaintiff Barr Laboratories, Inc. prays that:

(a) The Complaint of AstraZeneca LP, Aktiebolaget Draco, KBI Inc. and KBI-E Inc. be dismissed with prejudice;

(b) The manufacture, use, offer to sell, sale and/or importation into the United States of Barr Labs' ANDA product be declared not to infringe, induce infringement, or contribute to infringement by another of any claim of the '340 patent;

(c) The manufacture, use, offer to sell, sale and/or importation into the United States of Barr Labs' ANDA product be declared not to infringe, induce

infringement, or contribute to infringement by another of any claim of the '602 patent;

(d) The '340 patent be declared invalid;

(e) The '602 patent be declared invalid;

(f) Barr Labs be awarded its costs in this action;

(g) Barr Labs be awarded its attorney's fees pursuant to 35 U.S.C. § 285; and

(h) Barr Labs be awarded such other and further relief as this Court may deem just and proper.

JURY DEMAND

Defendant Barr Labs demands trial by jury as to all issues so triable.

Dated: June 12, 2008

Respectfully submitted,

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